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## NOTICE OF ALLOWANCE AND FEE(S) DUE

41838 7590 10/01/2010

GENERAL ELECTRIC COMPANY (PCPI)  
C/O FLETCHER YODER  
P. O. BOX 692289  
HOUSTON, TX 77269-2289

EXAMINER

NGUYEN, TRAN N

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 10/01/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/065,159

09/23/2002

John Eric Tkaczyk

RD-28334

4870

TITLE OF INVENTION: METHODS AND SYSTEMS FOR MANAGING CLINICAL RESEARCH INFORMATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	01/03/2011

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
Commissioner for Patents  
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or Fax (571)-273-2885**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

41838 7590 10/01/2010

**GENERAL ELECTRIC COMPANY (PCPI)  
C/O FLETCHER YODER  
P. O. BOX 692289  
HOUSTON, TX 77269-2289**

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/065,159 09/23/2002 John Eric Tkaczyk RD-28334 4870

**TITLE OF INVENTION: METHODS AND SYSTEMS FOR MANAGING CLINICAL RESEARCH INFORMATION**

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional NO \$1510 \$300 \$0 \$1810 01/03/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
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NGUYEN, TRAN N 3626 705-002000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_
- 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

**NOTE:** The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 2022 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 2022 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/065,159	TKACZYK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Tran Nguyen	3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the BPAI decision on 08/09/2010.
2. ☒ The allowed claim(s) is/are 1-40.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date ____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date ____.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other ____.</li> </ol> |
|---|---|

/Tran Nguyen/  
Examiner, Art Unit 3626

/Robert Morgan/  
Supervisory Patent Examiner, Art Unit 3626

**DETAILED ACTION**

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patrick S. Yoder, Attorney for Applicant, on 08/25/2010.

Please amend the application as follows:

1. (currently amended) A method for managing clinical study (CS) information for a clinical research entity via a server system computer coupled to a centralized database and at least one client system computer, said method comprising:
  - receiving at the server system computer CS information relating to at least one patient involved in a clinical study, the CS information being entered through a user selected template displayed on the client system computer, wherein the user selected template is selected from a plurality of templates stored in a centralized database, each of the plurality of templates configured to correspond to specific clinical studies;
  - storing CS information received at the server system computer in the centralized database;
  - tracking CS information stored in the centralized database;
  - updating the centralized database periodically with newly received information to maintain CS information; and
  - providing CS information in response to an inquiry.
2. (currently amended) A method in accordance with claim 1 further comprising transmitting from the server system computer to the at least one client system computer at least one report summarizing information and findings for a clinical study.
3. (currently amended) A method in accordance with claim 1 further comprising transmitting from the server system computer to the at least one client system computer at least one report summarizing CS information and findings for at least one patient involved in a clinical study.

4. (currently amended) A method in accordance with Claim 1 further comprising providing at least one medical device in communication with the at least one client ~~system~~ computer, the at least one medical device includes at least one of a computed tomography device, a radiography device, a positron emission tomography device, and an ultrasound imaging device.

5. (currently amended) A method in accordance with claim 4 wherein receiving CS information comprises:  
using a template selected by a user from the plurality of templates stored in the centralized database to gather protocols for operating the at least one medical device;  
displaying the template on the client ~~system~~ computer;  
operating the at least one medical device based on the entered protocols; and  
receiving at the server ~~system~~ computer information generated as part of the operation of the at least one medical device including at least one of x-rays and diagnostic images for a patient involved in a clinical study.

6. (currently amended) A method in accordance with claim 1 wherein receiving CS information comprises:  
using a template selected by a user from the plurality of templates stored within the centralized database to gather CS information;  
displaying the selected template on the client ~~system~~ computer; and  
inputting into the selected template at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment,

and any other documents and information relating to the treatment and/or diagnosis patient involved in a clinical study conducted by the clinical research entity.

7. (currently amended) A method in accordance with claim 1 wherein tracking CS information comprises:

compiling a data report including at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information relating to utilized medical equipment, engineering information relating to utilized medical equipment, marketing information relating to utilized medical equipment, and any other information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity; and

transmitting the data report to a predesignated party at the at least one client ~~system~~ computer.

8. (original) A method in accordance with claim 1 wherein tracking CS information comprises exporting CS information selected by a user to at least one computer program.

9. (currently amended) A method in accordance with claim 1 wherein tracking CS information further comprises:

linking to a specific patient involved in a clinical study at least one of a patient medical history, utilized medical application information, utilized medical equipment information, treatment diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information



and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis of the patient; and

displaying on the client ~~system~~ computer at least one of the patient medical history, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of the patient.

10. (currently amended) A method in accordance with claim 1 wherein providing CS information comprises:

displaying on the client ~~system~~ computer at least one of a list of patients involved in a clinical study and a list of clinical studies conducted by the clinical research entity;  
receiving an inquiry from the client ~~system~~ computer regarding at least one of a patient included within the patient list and a clinical study included within the clinical study list.

11. (currently amended) A method in accordance with claim 1 wherein providing CS information comprises:

receiving an inquiry from the client ~~system~~ computer regarding at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment

and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity; and

displaying information on the client ~~system~~ computer regarding at least one of the patient name, the patient sex, the patient medical history, the patient weight, the patient height, the patient age, the patient ID number, the modality of treatment diagnosis, utilized medical application information, utilized medical equipment information, treatment diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of the patient.

12. (currently amended) A method in accordance with claim 1 wherein providing CS information comprises:

accessing the centralized database;  
searching the database regarding the specific inquiry;  
retrieving information from the database; and  
transmitting the retrieved information to the client ~~system~~ computer for display by the client ~~system~~ computer.

13. (currently amended) A method in accordance with claim 1 further comprising connecting the client ~~system~~ computer and the server ~~system~~ computer via a network that includes one of a wide area network, a local area network, an intranet and the Internet.

14. (currently amended) A method for managing clinical study (CS) information for a clinical research entity via a server ~~system~~ computer coupled to a centralized database and at least one client ~~system~~ computer, the at least one client ~~system~~ computer in communication with at least one medical device, said method comprising:

using a template selected by a user from a plurality of templates stored in a centralized database to gather protocols for acquisition of image data via the at least one medical device, each of the plurality of templates configured to correspond to specific clinical studies;

operating the at least one medical device for acquiring image data based on the entered protocols;

receiving at the server ~~system~~ computer CS information that relates to at least one patient involved in a clinical study, the CS information being entered through the user selected template displayed on the client ~~system~~ computer and being generated as part of the operation of the at least one medical device including acquisition of diagnostic images;

storing CS information received at the server ~~system~~ computer in the centralized database;

tracking CS information stored in the centralized database;

updating the centralized database periodically with newly received CS information to maintain CS information;

providing CS information in response to an inquiry; and

transmitting from the server ~~system~~ computer to the at least one client ~~system~~ computer at least one report relating to CS information and findings for at least one of a clinical study and a patient involved in a clinical study.

15. (original) A method in accordance with claim 14 further comprising providing at least one medical device including at least one of a computed tomography device, a radiography device, a positron emission tomography device, and an ultrasound imaging device.

16. (currently amended) A method in accordance with claim 14 wherein receiving CS information comprises:

receiving at the server ~~system computer~~ at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity.

17. (currently amended) A network based system for managing clinical study (CS) information, said system comprising:

a client ~~system computer~~ comprising a browser;

a centralized database, stored on a tangible computer-readable medium, for storing information and a plurality of templates; and

a server ~~system computer~~ configured to be coupled to said client ~~system computer~~ and said database, said server ~~system computer~~ further configured to:

receive CS information relating to at least one patient involved in a clinical study, said CS information being entered through a user selected template displayed on said client ~~system computer~~, wherein the user selected template is selected from the plurality of templates stored in the centralized database, each of the plurality of templates configured to correspond to specific clinical studies;

store CS information in said centralized database;

track CS information;

update said centralized database periodically with newly received CS information to maintain CS information; and

provide CS information in response to an inquiry by a user.

18. (currently amended) A system in accordance with claim 17 wherein said server system computer is further configured to transmit to said client system computer at least one report summarizing CS information and findings for a clinical study.

19. (currently amended) A system in accordance with claim 17 wherein said server system computer is further configured to transmit to said client system computer at least one report summarizing CS information and findings for at least one patient involved in a clinical study.

20. (currently amended) A system in accordance with claim 17 further comprising at least one medical device in communication with said client system computer and said server system computer, said at least one medical device including at least one of a computed tomography device, a radiography device, a positron emission tomography device, and an ultrasound imaging device.

21. (currently amended) A system in accordance with claim 20 wherein said server system computer further comprises a receiving component that:

- uses a template selected by a user from said plurality of templates stored in said centralized database to gather protocols for operating said at least one medical device;
- displays said selected template on said client system computer;
- operates said at least one medical device based on said entered protocols; and
- receives CS information generated as part of the operation of said at least one medical device including at least one of x-rays and diagnostic images for a patient involved in a clinical study.

22. (currently amended) A system in accordance with claim 17 wherein said server system computer further comprises a receiving component that:

- uses a template selected by a user from said plurality of templates stored in said centralized database to gather CS information;

displays said selected template on said client ~~system~~ computer; and  
receives through said selected template at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient-age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity.

23. (currently amended) A system in accordance with claim 17 wherein said server ~~system~~ computer further comprises a tracking component that:

compiles a data report including at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information relating to utilized medical equipment, engineering information relating to utilized medical equipment, marketing information relating to utilized medical equipment, and any other information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity; and

transmits said data report to a predesignated party at said client ~~system~~ computer.

24. (currently amended) A system in accordance with claim 17 wherein said server ~~system~~ computer further comprises a tracking component that exports CS information selected by a user to at least one computer program.

25. (currently amended) A system in accordance with claim 17 wherein said server ~~system~~ computer further comprises a tracking component that:

links to a specific patient involved in a clinical study at least one of a patient medical history, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis of said patient; and

displays on said client ~~system~~ computer at least one of said patient medical history, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of said patient.

26. (currently amended) A system in accordance with claim 17 wherein said server ~~system~~ computer further comprises a providing component that:

displays on said client ~~system~~ computer at least one of a list of patients involved in a clinical study and a list of clinical studies conducted by the clinical research entity; and

receives an inquiry from said client ~~system~~ computer regarding at least one of a patient included within said patient list and a clinical study included within said clinical study list.

27. (currently amended) A system in accordance with claim 17 wherein said server ~~system~~ computer further comprises a providing component that:

receives an inquiry from said client ~~system~~ computer regarding at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity; and

displays information on said client ~~system~~ computer regarding at least one of said patient name, said patient sex, said patient medical history, said patient weight, said patient height, said patient age, said patient ID number, said modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of said patient.

28. (currently amended) A system in accordance with claim 17 wherein said server ~~system~~ computer further comprises a providing component that:

- accesses said centralized database;
- searches said database regarding a specific inquiry;
- retrieves information from said database; and

transmits said retrieved information to said client ~~system~~ computer for display by said client ~~system~~ computer.



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29. (currently amended) A system in accordance with claim 17 wherein said ~~server system computer~~, said client ~~system computer~~, and said database are connected via a network that includes one of a wide area network, a local area network, an intranet and the Internet.

30. (currently amended) A network based system for managing clinical study (CS) information, said system comprising:

a client ~~system computer~~ comprising a browser;

at least one medical device in communication with said client ~~system computer~~;

a centralized database, stored on a tangible computer-readable medium, for storing information and a plurality of templates; and

a server ~~system computer~~ configured to be coupled to said client ~~system computer~~ and said database, said server ~~system computer~~ further configured to:

use a template selected by a user from the plurality of templates stored in the centralized database to gather protocols for acquisition of image data via the at least one medical device, each of the plurality of templates configured to correspond to specific clinical studies;

operate said at least one medical device for acquiring image data based on said entered protocols;

receive CS information relating to at least one patient involved in a clinical study, said CS information entered through a user selected template displayed on said client ~~system computer~~ and generated as part of the operation of said at least one medical device including acquisition of diagnostic images;

store CS information in said centralized database;

track CS information;

update said centralized database periodically with newly received CS information to maintain CS information;

provide CS information in response to an inquiry; and

transmit to said client system computer at least one report relating to CS information and findings for at least one of a clinical study and a patient involved in a clinical study.

31. (original) A system in accordance with claim 30 wherein said at least one medical device comprises at least one of a computed tomography device, a radiography device, a positron emission tomography device, and an ultrasound imaging device.

32. (original) A system in accordance with claim 30 wherein said server system computer further comprises a receiving component that:  
receives at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity.

33. (currently amended) A computer program embodied on a non-transitory computer readable medium for managing clinical study (CS) information, said program comprising a code segment that:

receives CS information relating to at least one patient involved in a clinical study through a user selected template displayed on a client system computer, wherein the user selected template is selected from a plurality of templates stored in a centralized database, each of the plurality of templates configured to correspond to specific clinical studies;

maintains a database by adding, deleting and updating CS information; tracks CS information;

provides CS information in response to an inquiry by a user; and

transmits to said client ~~system~~ computer at least one report summarizing CS information and findings relating to at least one of a clinical study and a patient involved in a clinical study.

34. (currently amended) A computer program in accordance with claim 33 further comprising a code segment that enables at least one medical device to communicate with said client ~~system~~ computer wherein said at least one medical device includes at least one of a computed tomography device, a radiography device, a positron emission tomography device, and an ultrasound imaging device.

35. (currently amended) A computer program in accordance with claim 34 further comprising a code segment that:

displays a template selected by a user on said client ~~system~~ computer;

uses said selected template to gather protocols for operating said at least one medical device;

operates said at least one medical device based on said entered protocols; and

receives CS information generated as part of the operation of said at least one medical device including at least one of x-rays and diagnostic images.

36. (currently amended) A computer program in accordance with claim 33 further comprising a code segment that:

displays a template selected by a user on said client ~~system~~ computer;

uses said selected template to gather CS information; and

receives through said selected template at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application

information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity.

37. (currently amended) A computer program in accordance with claim 33 further comprising a code segment that:

compiles a data report including at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information relating to utilized medical equipment, engineering information relating to utilized medical equipment, marketing information relating to utilized medical equipment, and any other information relating to the treatment and/or diagnosis of a patient involved in a clinical study conducted by the clinical research entity; and

transmits said data report to a predesignated party at said client ~~system~~ computer.

38. (currently amended) A computer program in accordance with claim 33 further comprising a code segment that:

links to a specific patient involved in a clinical study at least one of a patient medical history, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents and information relating to the treatment and/or diagnosis of said patient; and

displays on said client ~~system~~ computer at least one of said patient medical history, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays; manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of said patient.

39. (currently amended) A computer program in accordance with claim 33 further comprising a code segment that:

displays on said client ~~system~~ computer at least one of a list of patients involved in a clinical study and a list of clinical studies conducted by the clinical research entity; and

receives an inquiry from said the client ~~system~~ computer regarding at least one of a patient included within said patient list and a clinical study included within said clinical study list.

40. (currently amended) A computer program in accordance with claim 33 further comprising a code segment that:

receives an inquiry from said client ~~system~~ computer regarding at least one of a patient name, a patient sex, a patient medical history, a patient weight, a patient height, a patient age, a patient ID number, a modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of the patient involved in a clinical study conducted by the clinical research entity; and

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displays information on said the client ~~system~~ computer regarding at least one of said patient name, said patient sex, said patient medical history, said patient weight, said patient height, said patient age, said patient ID number, said modality of treatment and/or diagnosis, utilized medical application information, utilized medical equipment information, treatment and/or diagnosis results, modeled images, x-rays, manufacturing information and documents relating to utilized medical equipment, engineering information and documents relating to utilized medical equipment, marketing information and documents relating to utilized medical equipment, and any other documents or information relating to the treatment and/or diagnosis of said patient.

***Allowable Subject Matter***

The following is an examiner's statement of reasons for allowance:

As per claim 1, the primary reason for allowance is the BPAI decision on 08/09/2010 (page 4-6).

The closest available prior art of record are as follows:

Brown (6196970) teaches a method capable of processing research data (Abstract); however, Brown does not teach the features discussed on page 4-6 of the BPAI decision.

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Lamb (Bridging the Gap between Drug Discovery and Market. Introduction: The Rise of Contract Research Organizations, mailed 06/21/2007) teaches contracting research organizations; however, Lamb does not remedy the deficiencies of Brown as discussed above.

A search for foreign patent was also conducted; however, no relevant art was found.

As per claims 2-13, these claims are also allowed for at least the same rationale as applied to claim 1 above, and incorporated herein.

As per claims 14-40, these claims are also allowed for at least the same rationale as applied to claims 1-13 above, and incorporated herein.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-

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270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert W. Morgan can be reached on 571-272-6773. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tran Nguyen/

Examiner, Art Unit 3626

09/23/2010

/Robert Morgan/

Supervisory Patent Examiner, Art Unit 3626